



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Stanley Zinberg, M.D.
The American College of Obstetricians and Gynecologists
P. O. Box 96920
Washington, DC 20090-6920

DEC 11 2000

Dear Dr. Zinberg:

This is in response to your letter of October 26, 2000, to me regarding Cytotec (misoprostol).

We note that your letter discusses issues identical to those raised in a citizen petition filed by Dr. Ralph W. Hale on behalf of your organization. The citizen petition requested that we require the withdrawal of the letter that G. D. Searle issued on August 23, 2000, regarding misoprostol. The petition also requested that we review the misoprostol labeling of March 6, 2000, and June 29, 2000, and rescind any contraindications for use of misoprostol in pregnancy that are not warranted by scientific evidence. A copy of your letter will be sent to the Dockets Management Branch to be included with documents related to the citizen petition filed by Dr. Hale. The petition has been assigned docket number 00P-1603.

A copy of our response to the petition will be provided to you upon its completion.

Thank you for sharing The American College of Obstetricians and Gynecologists Committee report with us.

Sincerely,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

00P-1603

AKS 1